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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,793	09/19/2003	Edward J. Kaplan	KAP 100 CIP	6738

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,793	KAPLAN, EDWARD J.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-35* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 22-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/01/06 & 12/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see page 1, line 1, filed December 27, 2006, with respect to the rejection(s) of claim(s) 34 under 112 (1) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Zamor et al (US 2001/0044567).

2. Applicant's arguments, see 2, filed December 27,2006, with respect to the rejection(s) of claim(s) 16 and 21 under 112(2) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Zamor et al (US 2001/0044567).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "strand or seed formed of a synthetic polymer, an inorganic material, a natural material or a shape memory material" in claims 2-5 is a relative term which

renders the claims indefinite. The term "strand or seed formed of a synthetic polymer, an inorganic material, a natural material or a shape memory material" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear whether strand or seed of the instant claims contain of a synthetic polymer, an inorganic material, a natural material or a shape memory material as a part of component (a) or (b) found in claim 1, or additional component therein. Therefore, the subject matter composed in claims 2-5 is not clear.

6. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The term "synthetic hemoglobin-like substances" in claim 15 is a relative term which renders the claim indefinite. The term "synthetic hemoglobin-like substances" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Whether the "synthetic hemoglobin-like substances" is a molecule, which is equivalent to hemoglobin in structure or one having same, physiological properties for enhancing oxygen perfusion must be clearly mentioned.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-14,16-20 and 22-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Zamora et al. (US 2001/0044567).

With respect to claims 1-14,16-20 and 22-35 the patent '567 discloses a branchytherapy device comprising a biocompatible biodegradable component (i.e. polymeric material), a non-radioactively therapeutic component and a biodegradable radiopaque marker (see abstract). The biodegradable component includes polymers (e.g. Poly (D,L-lactide) pooly (L-lacatide, (polyglycolide, poly (L-lactide-co-glycolide) that are same as those claimed (see page 2, para 0025 and page 5, para 0055). And also the biocompatible polymer such as poly(hydroxybutyrate) is included that can read as biocompatible elastic carrier to form an elastic brachytheraphy seed (see page 4, para 0049) since they are essential same compounds. The size and shape of the seeds are within the scope of those claimed (see page 5, para 0057+). The non-radioactive therapeutic component includes chemotherapeutic agent such as cisplatin bleomycin, a radiosensitizer drug such as 5-halo uracil compounds (see page 7, para 0080). Zamora

also teaches the radiopaque marker which includes various markers that are biodegradable such as platinum, tantalum and bismuth (see page 4, para 0051), where these markers are same as one required by claims, thus non-radionuclide imaging marker requirement is inherently met. The seeds of the device may be implanted singly, or may utilize suture strands, webs, meshes or other means to group the devices in a desired manner (see page 7, para 0085+). Methods of making the seeds are disclosed on pages 5-8, which include the steps as claimed.

Since, all the critical elements as required by instant claims are taught by the cited reference and claims are thus anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zamora (US 2001/0044567) in view of Widder et al (US 4,247,406).

Claims 15 is drawn to a branchytherapy strand or seed for implantation into a subject comprising, a non-radionuclide imaging marker, and a biocompatible carrier, and further comprising an additive material such as ferromagnetic microspheres, oxygen, hemoglobin or drugs for enhancing oxygen perfusion.

Zamora discloses a branchytherapy device comprising a bicompitable biodegradable (i.e. polymeric material), a non-radioactively therapeutic component and a biodegradable radiopaque marker (see abstract).

Zamora fails to disclose the said additives (e.g.ferromagnetic micropshers). However the inclusive of said additives into the brachytherapy strand or seeds well known in the art as shown by Widder.

Widder discloses a composition comprising microsphers formed from natural amino acid (proteins) and synthetic amino acid polymer, with magnetic particles embedded therein. The preferred polymer is human serum albumin and water soluble protein such as hemoglobin (see column 3, lines 62+).

It would have been obvious to one of ordinary skill in the art to modify the brachytherapy device form disclosed by Zamora to include microspheres formed from natural amino acid (proteins) with magnetic particles embedded as a carrier for administering water-soluble chemotherapeutic agents because Widder teaches that the incorporation of microspheres derived from natural amino acids (proteins) or hemoglohin containing magnetic particles as vehicles for site specific delivery of water-soluble chemotherapeutic agents, such as anti-cancer agents, whose use is now limited because of adverse side effects.

Because the microspheres which are formed from natural amino acids (proteins) and synthetic amino acids are biodegradable by proteolytic enzyme action, one of ordinary skill in the art would have been motivated to incorporate the microspheres formed from natural amino acid (proteins) with magnetic particles embedded therein

branchytherapy seeds advanced by Zamora. Based on the teaching of Widder, there is reasonable expectation that the microspheres containing ferromagnetic particles in drug delivery system would be highly desirable for administering water-soluble chemotherapeutic agents over extended period of time with low toxicity. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate or make use of the microspheres containing ferromagnetic particles in drug delivery system advanced by Zamora in view of the Widder teaching.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14,16-20, 22-24 and 27-35 are rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1-3, 5,10,12,15,

30, 32, 35 and 36 of US 6,746,661 B2. Although the conflicting claim is not identical, they are patentably distinct from each other because claim of the instant application is drawn to a brachytherapy strand or seed for implantation into a subject comprising, a non-radionuclide imaging marker, and a biocompatible carrier, wherein the strand or seed is elastic and has size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge), while the US pat. Application is a branchy therapy seed for implantation into a subject comprising one or more micropsheres, wherein each microsphere comprises at least one component selected from the group consisting of biocompatible component, a therapeutically active component and a radiopaque marker; the seed comprises a plurality of microspheres comprising a biocompatible component, one or more therapeutically active components, and a radiopaque marker; and brachytherapy seed has a size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge). Both require brachytherapy seeds, biocompatible component, radiopaque marker and therapeutic agent. Thus, the instant claim is within the scope of the claim of the US pat. Application. Thus scope is overlapping each other and properly included in the rejection because hey are patentably distinct from each other. Thus, the claim is readily envisaged by the teaching of the prior art and the claim is properly included in the rejection.

Claims 25 and 26 are rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1-3 of US 6,514,193 B2. Although the conflicting claim is not identical, they are patentably distinct from each other

because claim of the instant application is drawn to a method for administering a therapeutically active component to a target tissue in a subject, the method comprising implanting a brachytherapy strand or seed comprising, a non-radionuclide imaging marker, and a biocompatible carrier, wherein the strand or seed is elastic, and has a size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge), while the US Pat. Application is a method for administering a therapeutically active component to a target tissue in a subject, comprising the steps of providing a brachytherapy seed comprising a non-metal biocompatible component, a therapeutically active component comprising a non-radioactive drug, and a radiopaque marker, said biocompatible component being (a) physically associated with a therapeutically active component and (b) in contact with said radiopaque marker, wherein said brachytherapy seed has a size and shape suitable for passing through the bore of a needle having an interior diameter of less than about 2.7 millimeters (10 gauge). Both require brachytherapy seeds, biocompatible component, radiopaque marker and therapeutic agent. Thus, the instant claim is within the scope of the claim of the US pat. Application. Thus scope is overlapping each other and properly included in the rejection because hey are patentably distinct from each other. Thus, the claim is readily envisaged by the teaching of the prior art and the claim is properly included in the rejection.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VICKIE KIM
PRIMARY EXAMINER

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr